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December 28, 2007

BY ECF & FEDERAL EXPRESS

Honorable Peter G. Sheridan, U.S.D.J.
United States District Court
District of New Jersey
Martin Luther King, Jr. Federal
Building and Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: Bayer Schering, et al. v. Barr Laboratories, Inc.
Civil Action No. 05 CV 2308 (PGS) (ES)

Dear Judge Sheridan:

For the first time in their Proposed Findings of Fact and Conclusions of Law, Plaintiffs raise an issue that has never been briefed or discussed with the Court before. Plaintiffs assert that Barr waived its right to seek claim construction, or, in the alternative, Plaintiffs request a separate claim construction hearing. Please accept this letter on behalf of Defendant Barr Laboratories, Inc. ("Barr") in response to these contentions. Plaintiffs' assertion that Barr waived claim construction is both legally and factually incorrect, as explained in more detail below. Moreover, Barr does not believe that a separate claim construction hearing would be necessary or useful at this time; however, if Your Honor wishes to conduct such a hearing, Barr would not object.

First, Barr has not waived claim construction. Despite Plaintiffs' suggestions to the contrary, claim construction issues were addressed in Barr's discovery requests. On January 29, 2007, Barr served Plaintiffs with Barr's Third Set of Interrogatories. Interrogatory no. 1 specifically requested that Plaintiffs "[p]rovide a claim chart setting forth Plaintiffs' construction of each of the asserted claims of the '531 patent, including a detailed explanation of Plaintiffs' asserted construction for these patent claims, and identify the three persons with the most knowledge concerning Plaintiffs' asserted claim construction." (See Plfs.' Resp. to Int. No. 1 of Barr's Third Set of Int., attached hereto as Ex. 1.)

In response, Plaintiffs refused to provide any claim construction, refused to provide any support for any proposed claim construction, and refused to identify any persons

WINSTON & STRAWN LLP

Honorable Peter G. Sheridan, U.S.D.J.
December 28, 2007
Page 2

with knowledge of Plaintiffs' proposed claim construction. (*Id.*) Instead, Plaintiffs asserted that "[t]here are currently no claim terms in dispute." (*Id.*) Plaintiffs never supplemented this answer.

Then, at trial, Plaintiffs called an expert, Dr. Lee Shulman, who admitted that he is not one of ordinary skill in the art, and who purported to offer opinion testimony that several *additional* terms should be inserted into the asserted claims. In particular, Dr. Shulman opined that the terms should be altered to include the concepts of "99 % effective", "compliance" with the drug regimen, capable of administration in a "one size fits all" formulation, and effective in "American" women. (Tr. Vol. 9, 50:3-9, 55:12-14, 33:22-25, 10:12-22.) These terms do not appear in the claims and are not supported by the patent specification.

There is literally nothing in the plain language of the claims, the specification or the file history that even remotely supports Plaintiffs' attempt to insert these terms into the claims. Further, Dr. Shulman's opinion that these terms should be inserted into the claims is not supported by any authoritative treatise, Plaintiffs offered no evidence that Dr. Shulman's opinions would be accepted by a person of ordinary skill in the art, and Dr. Shulman admitted that he is not a person of skill in the art. (See Tr. Vol. 9, 49:2-22 (Dr. Shulman admitted that he is not qualified to testify to the understanding of one of ordinary skill in the art)). Accordingly, as set forth in Barr's Proposed Findings of Fact and Conclusions of Law, Dr. Shulman's testimony is exactly the type of "conclusory, unsupported assertion[] by experts as to the definition of a claim term" that the Federal Circuit rejected in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (holding that the words in a patent claim must "generally [be] given their ordinary and customary meaning unless an altered meaning is clearly indicated in the patent specification"), *cert. denied*, 126 S. Ct. 1332 (2006).

Here, Barr certainly did not waive claim construction, and is entitled to respond to Plaintiffs' last ditch effort at trial to change their discovery responses and alter the claims from their plain meaning as supported by the '531 patent's specification. If any party waived claim construction, it was Plaintiffs, by failing to supplement their response to Barr's interrogatory seeking Plaintiffs' proposed claim construction and support therefor. Plaintiffs' suggestion that they provided Barr with timely notice of their proposed claim construction in the expert report of Dr. Schulman is misplaced. The Pre-Trial Scheduling Order in this case did not provide for Reply Expert Reports, except as limited to secondary considerations of non-obviousness. (Scheduling Order, D.I. 94.)

Further, Plaintiffs' suggestion that a claim construction hearing was required prior to trial is legally incorrect. The Federal Circuit has held that "district courts are not required to follow any particular procedure in conducting claim construction." *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1358 (Fed. Cir. 2001); *see also Cytologix Corp. v. Ventana Med. Sys.*, 424 F.3d 1168, 1172 (Fed. Cir. 2005) ("the district court has considerable latitude in determining when to resolve issues of claim construction"). A "trial court may

WINSTON & STRAWN LLP

Honorable Peter G. Sheridan, U.S.D.J.
December 28, 2007
Page 3

exercise its discretion to interpret the claims at a time when the parties have presented a full picture of the claimed invention and the prior art.” *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996). In fact, courts have recognized that it may be appropriate to wait until the actual trial and rule upon claim construction at that time. *Elf Atochem N. Am. v. Libbey-Owens-Ford Co.*, 894 F. Supp. 844, 850 (D. Del. 1995) (“In a bench trial, the court can delay resolution of the claim construction issue until all of the evidence has been presented.”); *Moll v. Northern Telecom, Inc.*, C.A. 94-5451, 1995 U.S. Dist. LEXIS 18314, at *9 (E.D. Pa. Dec. 11, 1995) (court may wait until trial to conduct claim construction) (attached hereto as Ex. 2). Therefore, it would be wholly proper for the Court to construe the claims at this time without any prejudice to the Plaintiffs, particularly given Plaintiffs’ last-minute effort to insert unsupported terms into the claims and the fact that they have already presented their witness on claim construction at trial.

In sum, it is clear that Barr did not waive claim construction. Rather, Plaintiffs improperly attempted to add a number of terms to the asserted claims at trial by calling an expert who admittedly is not a person of ordinary skill in the art. Barr is entitled to respond to Plaintiffs’ attempt to add these terms, which it did through the cross examination of Dr. Shulman and in its Proposed Findings, and is willing to rest on its discussion of claim construction issues in its Proposed Findings of Fact and Conclusions of Law. Nevertheless, if Your Honor believes it would be helpful to hold an additional hearing on claim construction issues, Barr would not object to such a hearing.

Respectfully submitted,



James S. Richter

cc: All counsel of record